

Phyllis Collins, EdD, RN, CS-FNP
President

NYSNA

NEW YORK STATE NURSES ASSOCIATION

Martha L. Orr, MN, RN, CAE
Executive Director

11 Cornell Road, Latham, New York 12110-1499

Phone: 518-782-9400 Fax: 518-782-9530 E-mail: info@nysna.org <http://www.nysna.org>

October 27, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane; Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0313
Surgeon's and Patient Examination Gloves; Reclassification

Dear Sir or Madam:

The New York State Nurses Association (NYSNA) supports the efforts of the Food and Drug Administration (FDA) to reclassify surgeon and patient examination gloves from Class I to Class II medical devices and, as such, subjecting them to the two proposed special controls.

NYSNA believes that the protein amounts for natural rubber latex gloves and the powder amounts for both powdered and powder-free surgeon and patient examination gloves recommended on the proposed standard are reasonable and appropriate starting points given the current state of research on these subjects. In addition, NYSNA supports the FDA proposed labeling and testing recommendations included in the proposed rule. However, this association notes that the proposed rule is lacking in language recommending testing that includes a glove's ability to resist penetration by viruses and other bloodborne pathogens. NYSNA believes that language to this effect should be included in the proposed standard. In addition, NYSNA experts voice concerns that standards for glove testing do not model typical workplace conditions. This association believes that this shortfall in the standards for glove testing should be also be addressed in the newly proposed rule.

In response to the FDA's Specific Request for Comments, NYSNA would support a requirement that all surgeon and patient examination gloves be powder-free and the proposed *recommendations* on powder and protein limits becoming *requirements*. NYSNA would object to the addition of exemption or variance language to the proposed rule.

The NYSNA thanks you for the opportunity to comment on this important rule and for your responsiveness to the concerns of the nursing and health care community about the dangers of natural rubber latex protein glove products.

Sincerely,



Nancey P. Agard, MS, RN
Associate Director
Practice & Governmental Affairs

NPA/mrd

98N-0313

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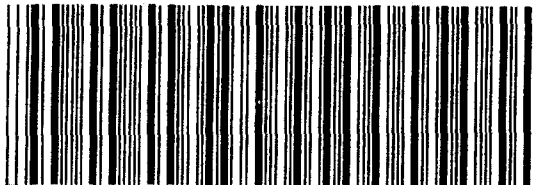
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